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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/728,248

**Applicant(s)**

DICARLO ET AL.

**Examiner**

RENE TOWA

**Art Unit**

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### DETAILED ACTION

1. This Office action is responsive to an amendment filed December 3, 2007. Claims 1-33 are pending. Claims 15 & 22 have been amended. No claim has been cancelled. No new claim has been added.

#### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claims 1-11, 15 & 20-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. (US Patent No. 5,368,045) in view of Kornberg et al. (US Patent No. 5,197,484).

In regards to **claims 1 & 15**, Clement et al. discloses a medical instrument system, comprising:

providing a medical instrument comprising:

a housing 8 having a proximal end 10 and a distal end 16;

a stylet 18 having a portion in the housing, the stylet 18 being movable between a first extended position and a first retracted position; and

a cannula 20 coaxially receiving the stylet 18 and having a portion in the housing 8, the cannula 20 being movable between a second extended position and a second retracted position (see figs. 1-2, 3a-d & 4a-4d; column 3/lines 4-16 & 22-32);

moving a stylet and a stylet block from a first position to a second position, the stylet block having an axially moveable first part and a second part attached to the stylet;

causing movement of the stylet; and,  
moving the cannula over the stylet (see claim 19 of Clement et al.).

In regards to **claim 2**, Clement et al. discloses a medical instrument further comprising a stylet block 36 attached to a proximal end of the stylet 18 and mounted inside the housing 8 (see fig. 2).

In regards to **claims 3 & 22**, Clement et al. discloses a medical instrument wherein the stylet block 36 comprises:

a first part inside the housing 8, the first part being moveable between an extended position and a retracted position (see fig. 2).

In regards to **claims 9 & 28**, Clement et al. discloses a medical instrument further comprising:

a stylet spring 44 capable of moving the stylet 18 from the first retracted position to the first extended position; and

a cannula spring 40 capable of moving the cannula 20 from the second retracted position to the second extended position (see fig. 2).

In regards to **claims 10 & 29**, Clement et al. discloses a medical instrument further comprising:

a first pivoting latch 52 capable of retaining the stylet 18 in a predetermined position when the stylet 18 is in the first retracted position; and

a second pivoting latch 60 capable of retaining the cannula 20 in a predetermined position when the cannula is in the second retracted position (see fig. 2).

In regards to **claims 11 & 30**, Clement et al. discloses a medical instrument wherein the stylet 18 comprises a notch 30 with a sharpened leading edge (see fig. 1c).

*Clement et al. disclose an instrument, as described above, that fails to teach a stylet configured to rotate when moved from the first retracted position to the first extended position.*

However, with respect to **claims 4-8, 20-21 & 23-27**, Kornberg et al. disclose an instrument including a second part 91 attached to a proximal end of a cannula 54, the second part 91 being rotatably engaged and in contact with a first part 55 and being able to rotate relative to an axis of the cannula 54;

wherein the housing 70 comprises a semi-cylindrical portion defining a track 158 configured to engage with the second part 91;

wherein the second part 91 comprises:

a projection 94 in contact with a track 158 associated with the housing 70, the projection 94 and track 158 capable of cooperating to axially rotate the second part 91 and the attached cannula 54 when the cannula 54 is moved between the first extended position and the first retracted position; wherein the track 158 is molded into the interior side of the housing 70;

wherein the track 158 is configured to provide unidirectional rotation to the cannula 54; wherein the track is configured to provide multidirectional rotation to the cannula 54 (see figs. 9,12,17 & 28; column 2/lines 1-9; column 3/lines 39-50 & 52-66; column 4/lines 29-31, 39-42 & 49-61; column 8/lines 18-23 & 25-32; column 9/lines 25-

40 & 53-61; column 10/lines 3-6 & 19-24; column 11/lines 27-34 & 46-53; column 12/lines 2-5, 25-32 & 40-47; column 13/lines 19-25; column 14/lines 26-34 & 45-47).

Applying the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) and are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Because both Clement et al. and Kornberg et al. teach biopsy instruments and since Kornberg et al. further teach a driving mechanism for simultaneously rotating and forwardly driving a cannula into body tissues, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an instrument similar to that of Clement et al. with a simultaneously rotating and forwardly driven stylet mechanism similar to that of Kornberg et al. in order to automatically rotate the stylet as it penetrates tissue so as to facilitate tissue penetration.

4. **Claims 12, 14, 31 & 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. ('045) in view of Kornberg et al. ('484) further in view of Kass (US 5,921,943).

Clement et al. as modified by Kornberg et al. disclose an instrument, as described above that teaches all the limitations of the claims except Clement et al. as modified by Kornberg et al. do not teach two openings and an opening opposing the notch. However, Kass discloses an instrument comprising a stylet including two

openings for a notch, which can also be viewed as a notch and an opening opposing the notch (which can be seen in Figure 19) for receiving tissue that has been cut by cutting cannula (see Column 9, lines 15-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Haaga with a notch having two openings and an opening opposing the notch, as taught by Kass, for receiving tissue that has been cut by cutting cannula.

5. **Claims 13 & 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. ('045) in view of Kornberg et al. ('484) further in view of Haaga (US Patent No. 5,394,887).

Clement et al. as modified by Kornberg et al. disclose an instrument, as described above that teaches all the limitations of the claims except Clement et al. as modified by Kornberg et al. do not teach a notch comprising a ramped surface.

However, Haaga teaches it is known to provide a stylet with notch having a ramped surface (see Figure 3 around elements 38 and 40), to secure the stylet in the tissue against withdrawal of the of the stylet while the cutting cannula is advanced forward to complete the cutting and capturing of the specimen in the notch (see Column 2, lines 52-55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Clement et al. as modified by Kornberg et al. with a stylet having a notch with a ramped surface, as taught by Haaga to secure the

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stylet in the tissue against withdrawal of the of the stylet while the cutting cannula is advanced forward to complete the cutting and capturing of the specimen in the notch.

6. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. ('045) in view of Kornberg et al. ('484) further in view of Burbank et al. (US 6,331,166).

Clement et al. as modified by Kornberg et al. discloses a method, as described above, that fails to explicitly teach a step of oscillating the stylet along the axis.

However, Burbank et al. discloses a method further comprising oscillating the stylet 18 along the axis (see column 7/lines 21-24).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Clement et al. as modified by Kornberg et al. in order to drill the stylet into the target tissue.

7. **Claims 17-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. ('045) in view of Kornberg et al. ('484) further in view of Ritchart et al. (US 5,649,547).

Clement et al. as modified by Kornberg et al. above disclose a method, as described above, that fails to teach the step of collecting a sample in a notch of the stylet.

However, Ritchart et al. disclose a method comprising the step of collecting a sample in a notch 28 of a stylet; wherein the method further comprises removing the sample from the notch 28 by inserting an object 22 through an opening located in the



notch 28 (see figs. 5-6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Clement et al. as modified by Kornberg et al. with a method step comprising removing the tissue through a notch similar to that of Ritchart et al. in order to conveniently collect the severed tissues (see Burbank et al., column 8/lines 39-46).

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Clement et al. as modified by Kornberg et al. and Ritchart et al. above with a step of removing the sample over an inclined surface since such a modification would amount to a design choice that would serve the same purpose of removing the severed tissue. Even moreover yet, the Applicant has not disclosed that removing the tissue over an inclined surface provides an advantage, is used for a particular purpose, or solves a stated problem.

### ***Response to Arguments***

8. Applicant's arguments filed December 3, 2007 have been fully considered but they are not persuasive. Applicant argues that it would not have been obvious to modify Clement et al. to arrive at the invention. This argument has been considered but has not been deemed persuasive.

In response to the Applicant's argument, the Examiner respectfully traverses. The Examiner notes that Kornberg teaches a system for rotating a cannula, which is part of a biopsy instrument that includes both a cannula and a stylet while Clement et al. teaches a biopsy instrument with both a cannula and a stylet as well. It is the Examiner's assertion that, in light of Graham factors cited supra and the KSR decision,

it would have been obvious to one of ordinary skill in the art, looking at both inventions, to modify Clement et al. to include a simultaneously rotating and linearly moving stylet or cannula.

In view of the foregoing, the rejections over Clement et al. and Kornberg are maintained.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RTT/

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736